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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,937	08/21/2007	Anna Cederholm	EPCL:015US/ 10613209	6786

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,937	CEDERHOLM ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-13* is/are pending in the application.

4a) Of the above claim(s) *1,6,8,9 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/02/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment, filed 08/21/2007, has been entered.

Claims 2 and 7 have been canceled.

Claims 1, 3-6 and 8-13 are pending.

Claims 1, 6, 8, 9 and 11-13 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions, there being no allowable generic or linking claim. Election was made *without* traverse in the reply filed on 07/28/2009.

Claims 3-5 and 10 are currently under examination as they read on a method of treating a subject at risk of atherothrombosis wherein the subject is a SLE patient.

Priority

The priority date for claims 3-5 and 10 is deemed the effective filing date of provisional application, USSN 60/521,385, i.e., 04/15/2004.

Specification

Applicant is requested to review the application for the use of trademarks, embedded hyperlinks and/or other form of browser-executable code or spelling error.

Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 08/02/2007 has been considered by the examiner.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The present claims are indefinite in the recitation of "a corresponding salt thereof" because the metes and bounds of the limitation are ambiguous and ill-defined. The instant specification discloses that a "*salt can be a pharmaceutically acceptable acid addition salt where the counter ion is, for example, chloride, acetate*" (see page 5, lines 20-21). However, the term "corresponding" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of how related a salt compound is in order to be a corresponding salt of Annexin V; and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of "a corresponding salt thereof".

Furthermore, the present claims are indefinite in the recitation of "N-terminal fragment of Annexin V" because the metes and bounds of the N-terminal fragment are ambiguous and ill-defined. The instant specification discloses that "*the N-terminal fragment of Annexin V is large enough to be recognisable by the skilled person as a fragment of Annexin V rather than, for example, a fragment of another annexin*" (see page 5, lines 12-14). However, the term "N-terminal" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree of what is considered N-terminal vs. C-terminal; and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of "N-terminal fragment" of Annexin V.

Applicant is invited to avoid the recitations of "a corresponding salt thereof" and "N-terminal fragment" in order to obviate this rejection.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add New Matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Allison (WO 02/067857 A2, cited on IDS, see entire document).

Allison taught a method of treating a subject at risk of atherothrombosis and/or plaque rupture comprising administering an effective amount of Annexin V (see, e.g., page 7, lines 13-16; page 8, lines 8-12; page 29, lines 15-24; page 30, lines 7-9). It is noted that the prior art taught that the subject is susceptible to or at risk of thrombosis (see page 30, lines 7-9), which reads on subject at risk of atherothrombosis and/or plaque rupture under the broadest reasonable interpretation. Furthermore, the prior art also taught administering to subjects after thrombosis which reads on subjects exhibiting vulnerable plaques (see page 30, lines 7-8). Therefore, Allison anticipates the present claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allison (WO 02/067857 A2, cited on IDS) in view of Pamuk et al. (Clin. Rheumatol. 2003, 22:336-338).

The teaching by Allison has been discussed supra (see above).

Allison did not teach the subject is a SLE patient. However, it would have been obvious to one of ordinary skill in the art to administer Annexin V to SLE patient as a patient at risk for atherothrombosis and/or plaque rupture in view of the teaching by Pamuk et al. (see entire document). In particular, Pamuk taught that atherothrombosis is quite common in SLE (see Abstract and Introduction). Upon reading the teaching by Pamuk et al., one of ordinary skill in the art would have reasonably expected to administer Annexin V, as an anticoagulant agent as taught by Allison, to SLE patients who is at risk for atherothrombosis. Furthermore, given that Allison et al. taught that Annexin V is useful for treating atherothrombosis and/or plaque rupture, one of ordinary skill in the art would have been motivated to use the prior art method for SLE patient given that atherothrombosis is quite common in SLE.

Furthermore, Allison did not teach the effective amount of Annexin V in the pharmaceutical composition is determined from a diagnostic status analysis of Annexin V-endothelium binding in said subject. However, the effective amount of Annexin V is a result effective variable which is related to the dosage range of the administration. Therefore, the person of ordinary skill in the art would have been able to select an effective amount of Annexin V by optimizing the dosage of Annexin V as a routine laboratory practice that is within his/her technical grasp. Furthermore, given that Allison taught that in-vivo thrombosis test can be performed to determine the appropriate annexin protein (see page 32, lines 11-28), and that Annexin V was known, at the time of the invention, to bind to endothelium (see pages 5-7); one of ordinary skill in the art would have been reasonably expected to perform a diagnostic analysis of Annexin V-endothelium binding to determine the effective amount of Annexin V to be administered.

Given the above discussion, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
October 25, 2009